

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 March 2002 (07.03.2002)

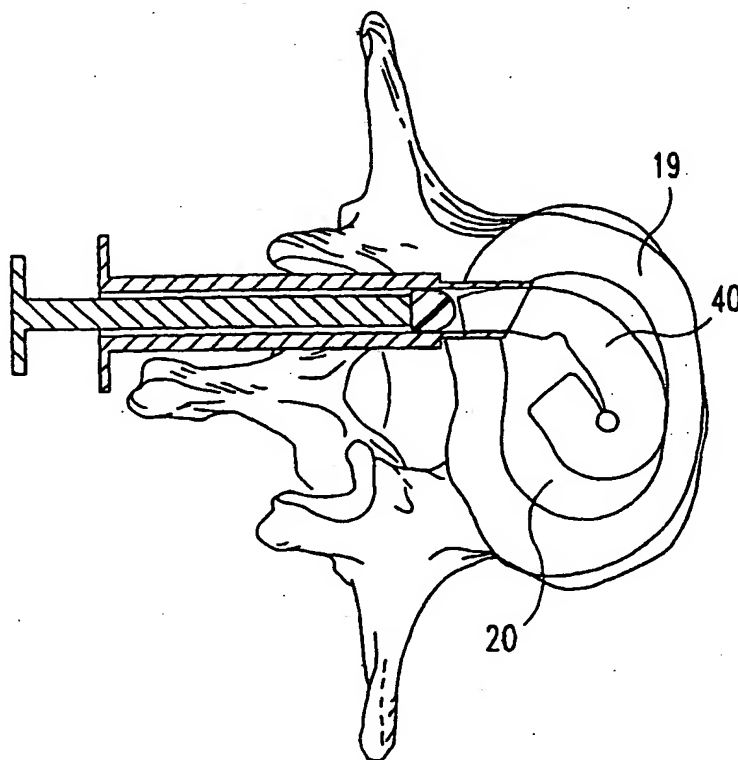
PCT

(10) International Publication Number
WO 02/017824 A3

- (51) International Patent Classification⁷: **A61F 2/44**, 2/46, A61L 27/14 (74) Agent: **THOMAS, Timothy, N.**; Woodard, Limhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).
- (21) International Application Number: **PCT/US01/26989**
- (22) International Filing Date: **30 August 2001 (30.08.2001)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data: **09/650,525** **30 August 2000 (30.08.2000)** **US**
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- (81) Designated States (national): **AE, AG, AI, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (regional): **ARIPO** patent (GH, GM, KI, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), **Eurasian** patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), **European** patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), **OAPI** patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
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[Continued on next page]

(54) Title: **INTERVERTEBRAL DISC NUCLEUS IMPLANTS AND METHODS**



(57) Abstract: Nucleus pulposus implants that are resistant to migration in and/or expulsion from an intervertebral disc space are provided. In one form of the invention, an implant includes a load bearing elastic body surrounded in the disc space by an anchoring, preferably resorbable, outer shell. In certain forms of the invention, the elastic body is surrounded by a supporting member, such as a band or jacket, and the supporting member is surrounded by the outer shell. Kits for forming such implants are also provided. In another form of the invention, an implant is provided that has locking features and optional shape memory characteristics. In yet another aspect of the invention, nucleus pulposus implants are provided that have shape memory characteristics and are configured to allow short-term manual, or other deformation without permanent deformation, cracks, tears, breakage or other damage. Methods of forming and implanting the implants are also described, as are delivery devices and components thereof for delivering the implants.

WO 02/017824 A3



Published:

*with international search report
with amended claims*

Date of publication of the amended claims:

3 July 2003

(88) Date of publication of the international search report:
6 March 2003

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AMENDED CLAIMS

[received by the International Bureau on 29 October 2002 (29.10.2002);
original claim 23 amended; new claims 86-88 added;
remaining claims unchanged (2 pages)]

23. An intervertebral disc nucleus pulposus implant, comprising:
a load bearing elastic body having shape memory and sized for
placement into an intervertebral disc space, said body having a first end, a second
end, and a central portion; wherein said shape memory biases said body to a first
configuration wherein said first end and said second end are positioned adjacent
to said central portion to form at least one inner fold and to provide a substantially
solid center core when the implant is in its first configuration; said elastic body
configurable into a second, straightened configuration for insertion through an
opening in an intervertebral disc annulus fibrosis; wherein said shape memory
returns said body to said first configuration after said insertion.

24. The implant of claim 23, wherein said inner fold defines an
aperture.

25. The implant of claim 23, wherein said elastic body is comprised of a
hydrogel material.

26. The implant of claim 23, wherein said elastic body is comprised of
an elastomer.

27. The implant of claim 26, wherein said elastomer is selected from
the group consisting of silicone, polyurethane, copolymers of silicone and
polyurethane, polyolefins, nitrile and combinations thereof.

28. The implant of claim 24, wherein said inner fold has a surface with
projections, said projections extending into said aperture.

29. The implant of claim 23, wherein said elastic body has an outer
surface, said outer surface having projections extending therefrom, said
projections configured for enhancing fixation of said body in said intervertebral
disc space.

end of said elongated housing member, said tip member sized and configured for delivery of a spinal disc implant through an aperture in an annulus fibrosus, said lumen of said tip member in communication with said lumen of said elongated housing member.

5 79. The device of claim 78, said device further comprising a plunger member, said plunger member disposed in said lumen of said elongated housing member.

10 80. The device of claim 78, wherein said top wall and said bottom wall both include an opening therethrough that extends from said proximal end of said tip member to said distal end of said tip member.

 81. The device of claim 80, wherein at least one of said top wall and said bottom wall has a surface that includes a surface roughening.

 82. The device of claim 81, wherein said surface roughening comprises teeth.

15 83. The device of claim 80, wherein one of said side walls has a length greater than the other of said side walls.

 84. The device of claim 78, wherein one of said side walls has a length greater than the other of said side walls.

20 85. The device of claim 78, wherein at least one of said top wall and said bottom wall has a surface that includes a surface roughening.

 86. The implant of claim 23 wherein said elastic body has a surface that includes wrinkles, indents or projections that relieve stress and prevent cracking or tearing of the implant when the implant is straightened for implantation.

25 87. The implant of claim 23 wherein said first configuration forms at least one inner fold without overlapping.

 88. The implant of claim 23 wherein in said first configuration the ends abutt without overlapping.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/26989

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/46 A61F2/46 A61L27/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 353 936 A (CEDAR SURGICAL INC) 7 February 1990 (1990-02-07) column 6, line 29 -column 7, line 42 column 8, line 44 -column 9, line 17 claims; figures	1-6, 9, 10, 12, 13, 16, 20-22, 52-58
X	EP 0 621 020 A (SULZER MEDIZINALTECHNIK AG) 26 October 1994 (1994-10-26)	23-27, 29, 38, 44, 78, 79
Y	page 2, line 35 -page 3, line 14 page 3, line 40 - line 53 page 4, line 19 - line 31 page 4, line 49 -page 5, line 13 claims 1-12; figures 1,6-8 -/-	34-37



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

21 August 2002

Date of mailing of the international search report

02.09.2002

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INTERNATIONAL SEARCH REPORT

 International Application No
 PCT/US 01/26989

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 712 486 A (CATON PHILIPPE ET AL) 24 May 1995 (1995-05-24)	46-49
Y	claims; figures	50, 51
P, X	WO 01 45577 A (SDGI HOLDINGS INC) 28 June 2001 (2001-06-28)	23-27
P, Y	page 2, line 25 - page 3, line 6; claims,	34-37, 50, 51
X	US 5 716 416 A (LIN CHIH-I) 10 February 1998 (1998-02-10)	46-51, 78-80
	claims 1-14; figures	
P, X	WO 01 06962 A (BAAT B.V. ENG ET AL) 1 February 2001 (2001-02-01)	23, 24, 38, 40, 41, 44, 46-49, 78-80
	claims; figures 1A-G, ,4, 5, 9A, 9B, ,12	
P, X	WO 01 28468 A (CAUTHEN RES GROUP INC) 26 April 2001 (2001-04-26)	71-80
	page 5, line 24 - page 6, line 16 page 7, line 5 - line 30 claims; figures 8-14	
A	WO 99 02108 A (WARDLAW DOUGLAS) 21 January 1999 (1999-01-21)	1-22, 52-58
	page 3, line 16 - page 6, line 24 claims; figures	
A	US 5 192 326 A (HIGHAM PAUL A ET AL) 9 March 1993 (1993-03-09)	1-22, 52-58
	claims; figures	
A	US 5 047 055 A (HIGHAM PAUL A ET AL) 10 September 1991 (1991-09-10)	1-22, 52-58
	claims; figures	
A	US 5 645 597 A (KRAPIVA PAVEL I) 8 July 1997 (1997-07-08)	1-22, 52-58
	column 3, line 4 - column 4, line 60; figures	
A	US 5 919 235 A (BAUMGARTNER WALTER ET AL) 6 July 1999 (1999-07-06)	23-51
	claims; figures	
A	DE 197 10 392 C (HAHNEL MICHAEL) 1 July 1999 (1999-07-01)	23-26, 28-33
	claims; figures	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/26989**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **59-70**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv), PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-22, 52-58

An intervertebral disc nucleus pulposus implant, comprising:
a load bearing elastic body sized for introduction into an intervertebral disk space, said body surrounded by a resorbable shell.

2. Claims: 23-51

An intervertebral disc nucleus pulposus implant, comprising:
a load bearing elastic body sized for placement into an intervertebral disc space, said body having a first end and a second end, said first end and said second end configured for mating engagement with each other, said elastic body having a first configuration wherein said first end and said second end are matingly engaged to each other, said elastic body configurable into a second, straightened configuration for insertion through an opening in an intervertebral disc annulus fibrosis, said body configurable back into said first configuration after said insertion.

3. Claims: 71-77

A spinal disc implant delivery device tip, comprising:
(a) a base member having a proximal end, a distal end and a lumen extending longitudinally therethrough; and
(b) a plurality of movable members, said movable members having a proximal end and a distal end, said proximal end of said movable members abutting said distal end of said base member, said movable members having a closed configuration defining a cavity in communication with said lumen of said base member, said members sized and configured for passage into an aperture in an annulus fibrosis.

4. Claims: 78-85

A spinal disc implant delivery device, comprising:
(a) an elongated housing member having a proximal end, a distal end and a lumen extending longitudinally therethrough;
(b) a tip member, said tip member having a top wall, a bottom wall, a first side wall, a second side wall, a proximal end, and a distal end, said walls defining a lumen extending longitudinally therethrough, said proximal end of said tip member connected to said distal end of said elongated housing member, said tip member sized and configured for delivery of a spinal disc implant through an